UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,145	08/04/2000	Chinnappa Kodira	CL000747	3253

7590 12/19/2001

Celera Genomics Corp.
Attn: Robert A. Millman, Patent Director
C2- 4 # 20
45 West Gude Drive
Rockville, MD 20850

EXAMINER	
WEGERT, SANDRA L	//

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/633,145	Applicant(s) KODIRA ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4,8,9,13 and 24-29* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement sent 11/20/01 has been entered into the record as Paper 10. Applicant's election with traverse of Invention III, (claims 4-5 and 8-11) in Paper No. 9 (20/November/01) is acknowledged. In addition, Applicant elected the following Group: SEQ ID NO: 2. Since SEQ ID NO: 2 is a polypeptide, and the elected invention comprises polynucleotides, the Examiner will search and examine the polynucleotide(s) that encode SEQ ID NO: 2. In Paper 9, claims 1-3, 5-7, 10-12 and 14-23 were cancelled by the Applicant. Claim 13 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected Invention, there being no allowable generic or linking claim. The Applicant traversed the restriction and argued that claim 13 should be rejoined with the polynucleotides of invention III. However, Claim 13 (Invention VII) and the claims of Invention III were restricted properly, because the methods of claim 13 and Invention III are independent and distinct in that they are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, and goals. The methods of claim 13 comprise using a complimentary mRNA or short cDNA probe to label a strand of nucleic acid. The methods require chromosomal isolation or tissue preparation and attachment of fluorescent antibody to the probe, as well as different reagents and method steps to label nucleic acids *in situ*. The methods of Invention III use vectors

and host cells to recombinantly *express* the protein of SEQ ID NO: 2. The method steps and goals of invention III involve production of a working plasmid and transfection of that vector into a suitable host cell that will produce the polypeptide.

Claims 4, 8, 9 and 24-29 are under examination in the current application.

Informalities

Specification

The disclosure is objected to because of the following informalities:

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "NUCLEIC ACID MOLECULES ENCODING HUMAN G-PROTEIN COUPLED RECEPTORS."

Appropriate correction is required.

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, especially 1.821, part (c), because *each* disclosure of a sequence embraced by the definitions set forth in the rules must be accompanied by the required reference to a unique sequence identifier (i.e., SEQ ID NO:). This occurs in Figs. 1, 2 and 3, for example.

Appropriate correction is required. Please submit either: New copies of Figs 1, 2 and 3 with SEQ ID NO's appropriately inserted, or copies of Figs 1, 2 and 3 containing line-numbering so that entry of amendments can be more easily facilitated.

Claim Rejections/Objections

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8, 9 and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, specific and substantial asserted utility or a well-established utility.

The claims are directed to recombinant expression of the peptide encoded by SEQ ID NO: 2 and the nucleic acids encoding SEQ ID NO: 2.

No well-established utility exists for newly-isolated complex biological molecules. However, the specification asserts the following as credible, specific and substantial patentable utilities for the claimed polypeptide and the polynucleotides and recombinant methods used to express it:

Each of these shall be addressed in turn:

1) For the production of antibodies;

2) To make hybridization probes and primers to detect nucleic acid molecules that encode the polypeptide of SEQ ID NO: 2 and to localize receptor expression in tissue samples;

3) To search for drugs as ligands or antagonists of the polypeptide encoded by the claimed polynucleotide;

4) To produce a variant or chimeric nucleotide or polypeptide;

5) In the creation of transgenic animals;

6) To detect polymorphisms in individuals;

7) For clinical therapy using the polypeptide or ligand.

Each of these shall be addressed in turn:

1) For the production of antibodies. This asserted utility is credible and substantial, but not specific. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, both the polypeptide and its antibodies have no patentable utility.

2) To make hybridization probes and primers to detect nucleic acid molecules that encode the polypeptide of SEQ ID NO: 2 and to localize receptor expression in tissue samples. This asserted utility is credible but not substantial or specific. Hybridization probes and primers can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) To search for drugs as ligands or antagonists of the polypeptide encoded by the claimed polynucleotide. This asserted utility is credible and specific. However, it is not substantial. The specification does not characterize the polypeptide encoded by the polynucleotide of the claimed invention. Therefore binding sites, etc. are not identified. Significant further experimentation would be required of the skilled artisan to characterize the protein and search for ligands. There is no disclosure for example, of how to assay for ligand binding and possible transduction mechanisms. It is not known the class of drugs to use or what measurements to perform. Since this asserted utility is not presented in mature form so it could be readily used in a real world sense, the asserted utility is not substantial.

4) To produce a variant or chimeric nucleotide or polypeptide. This asserted utility is credible but not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification discloses nothing specific or substantial for the variant nucleotide and polypeptide that is produced by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) In the creation of transgenic animals. This asserted utility is credible but not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated gene of the present invention. Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the claimed gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6) To detect polymorphisms in individuals. This asserted utility may be credible, however it is neither specific nor substantial. Applicants have not demonstrated the function of the polypeptide encoded by the claimed polynucleotide, much less relevant polymorphisms. Thus, the asserted utility is not substantial. Finally, many unrelated sequences can be polymorphic, generally. Thus, the asserted utility is not specific.

7) For clinical therapy using the polypeptide or ligand. This asserted utility is credible but not specific or substantial. Such can be performed for any polypeptide. Further, the specification does not disclose diseases associated with a the gene of the claimed invention or with the polypeptide encoded by the gene. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease and to determine the route of administration of the polypeptide or ligand, as well as quantity and duration of treatment. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Furthermore, the specification asserts that the claimed polynucleotide encodes a G-protein coupled receptor based on homology to known receptors. This assertion cannot be accepted as credible in the absence of supporting evidence of specific function, because the art shows that structurally similar receptors are unpredictably functionally dissimilar. Numerous examples from the receptor art demonstrate polypeptides with high homology having a wide-variety of functions in organisms (Ji, et al, 1998, JBC, 273:17299). Even closely-related family members sometimes work very differently and have different specific functions in the organism (Ji, et al, 1998, p. 17302, 3rd paragraph). Therefore, one skilled in the art would not know the utility and function of the claimed polynucleotide encoding the disclosed polypeptide, even if it were classified as a G-protein coupled receptor.

Claims 4, 8, 9 and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Due to the large quantity of experimentation necessary to determine an activity or property of the disclosed polypeptide encoded by the claimed polynucleotides such that it can be determined how to use the claimed polynucleotides and to screen for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of

the claims which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rendered indefinite because the specification does not teach how to recombinantly produce a polypeptide from the complementary nucleic acid (refer to claim 4(d)).

Conclusion: Claims 4, 8, 9, 24-29 are rejected for the reasons listed above.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

SLW

12/12/01